



DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning Certain Surgical Gowns

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection (CBP)

has issued a final determination concerning the country of origin of certain surgical gowns.

Based upon the facts presented, CBP has concluded in the final determination that the country of origin of the surgical gowns in question is the Dominican Republic for purposes of U.S.

Government procurement.

DATES: The final determination was issued on July 21, 2022. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination within [INSERT 30 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Marie Durané, Food, Textiles and Marking Branch, Regulations and Rulings, Office of Trade, at (202) 325-0984.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on July 21, 2022, U.S. Customs and Border Protection (CBP) issued a final determination concerning the country of origin of certain surgical gowns (Association for the Advancement of Medical Instrumentation (AAMI) Level 3 and Level 4 sterile disposable surgical gowns) for purposes of Title III of the Trade Agreements Act of 1979. This final determination, HQ H321354, was issued at the request of Global Resources International, Inc. (GRI) and Santé USA, LLC (Santé USA), under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511-18). In the final determination, CBP has

concluded that, based upon the facts presented, the country of origin of the surgical gowns is the Dominican Republic for purposes of U.S. Government procurement.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that notice of final determinations shall be published in the *Federal Register* within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the *Federal Register*.

Dated: July 21, 2022.

Alice A. Kipel,
Executive Director,
Regulations and Rulings,
Office of Trade.

HQ H321354

July 21, 2022

OT:RR:CTF:VS H321354 MJD

CATEGORY: Origin

Lawrence R. Pilon

Rock Trade Law LLC
134 North LaSalle Street
Suite 1800
Chicago, IL 60602

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Country of Origin of Surgical Gowns

Dear Mr. Pilon:

This is in response to your request of October 11, 2021, on behalf of your clients, Global Resources International, Inc. (“GRI”) and Santé USA, LLC (“Santé USA”), for a final determination regarding the country of origin of surgical gowns pursuant to Title III of the Trade Agreements Act of 1979 (“TAA”), as amended (19 U.S.C. § 2511 *et seq.*), and subpart B of Part 177, U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. § 177.21, *et seq.*). GRI and Santé USA are parties-at-interest within the meaning of 19 C.F.R. §§ 177.22(d) and 177.23(a) and are therefore entitled to request this final determination. A meeting was held with counsel for GRI and Santé USA by videoconference on April 12, 2022.

FACTS:

GRI and Santé USA are manufacturers, importers, exporters, and distributors of medical devices and supplies for the healthcare industry. The subject merchandise consists of the Association for the Advancement of Medical Instrumentation (“AAMI”) Level 3 and Level 4 disposable surgical gowns for use in hospitals, surgical centers, and similar healthcare settings. The surgical gowns are made from nonwoven synthetic spun-melt-spun (“SMS”) textile material and plastic film made in the United States. The SMS textile material forms the exterior of the gown, while the plastic film material is glued to the interior of the gown as reinforcement for the SMS textile material. According to GRI and Santé USA, the SMS textile material is the most expensive material in the finished product, accounting for 30% of the finished gown’s value, and makes up 100% of the gown’s exterior. The SMS textile material and plastic film are transferred in rolls to the Dominican Republic where they are cut into component parts, which are in turn assembled into two sleeve subassemblies and the gown body subassembly. The sleeve subassemblies and body gown subassemblies are then returned to the United States for final assembly consisting of principally attaching the sleeve subassemblies to the gown body subassembly and attaching the neck binding to the neck opening of the gown. A more detailed account of the manufacturing process of the surgical gowns is as follows:

United States:

- Production of the SMS textile material.
- Manufacture of plastic film.

Dominican Republic:

- The SMS textile material and plastic film are cut into the main gown body, sleeve, and reinforcement pieces using electric scissors.
- The SMS textile material is converted to waist ties using a tie-making machine.
- The sleeve cut piece is folded and its seam sealed by a bar heat sealer and ultrasonic welder sewing machine.
- The knit cuff is sewn to the formed sleeve piece using a sewing machine.
- The item number, level of performance claim, and brand information are

- stamped onto the main gown body piece.
- The hook and loop fastener material is sewn to the gown body using a sewing machine.
- The ties are attached to the gown body subassembly by glue and ultrasonic welding.
- Glue is applied evenly to the plastic film reinforcement piece and applied to the inner face of the gown body subassembly.

United States:

- The sleeve subassemblies are attached to the main gown body subassembly with an ultrasonic welder sewing machine.
- The neck binding is attached to the neck opening of the gown using a binding machine.
- Each gown is inspected for visible defects and conformity to required dimensions for size.
- The gowns are also tested for conformity to applicable AAMI Level 3 and Level 4 strength and permeability standards.
- Gowns are packaged and sterilized with ethylene oxide.

GR and Santé USA state that the SMS textile material is classified in heading 5603, Harmonized Tariff Schedule of the United States (“HTSUS”), which provides for “[n]onwovens, whether or not impregnated, coated, covered or laminated.” The finished surgical gowns are classified under subheading 6210.10.5010, HTSUSA, which provides for “[g]arments, made up of fabrics of heading 5602, 5603, 5903, 5906 or 5907: Of fabrics of heading 5602 or 5603: Other: Nonwoven disposable apparel designed for use in hospitals, clinics, laboratories or contaminated areas: Surgical or isolation gowns.”

ISSUE:

What is the country of origin of the surgical gowns for purposes of U.S. Government procurement?

LAW AND ANALYSIS:

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purpose of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III, Trade Agreements Act of 1979, as amended (19 U.S.C. §§ 2511-2518).

The rule of origin set forth in 19 U.S.C. § 2518(4)(B) states:

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 C.F.R. § 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with the Federal Acquisition Regulation. *See* 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulation restricts the U.S. Government’s purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. *See* 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulation defines “U.S.-made end product” as:

... an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

See 48 C.F.R. § 25.003.

The Federal Acquisition Regulation, 48 C.F.R. § 25.003 defines “designated country end product” as a:

WTO GPA [World Trade Organization Government Procurement Agreement] country end product, an FTA [Free Trade Agreement] country end product, a least developed country end product, or a Caribbean Basin country end product.

Section 25.003 provides that a “Free Trade Agreement country end product” means an article that-

- (1) Is wholly the growth, product, or manufacture of a Free Trade Agreement (FTA) country; or
- (2) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in an FTA country into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product, includes services (except transportation services) incidental to the article, provided that the value of those incidental services does not exceed that of the article itself.

“Free Trade Agreement country” means Australia, Bahrain, Canada, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Korea (Republic of), Mexico, Morocco, Nicaragua, Oman, Panama, Peru, or Singapore. *See* 48 C.F.R. § 25.003. Thus, the Dominican Republic is an FTA country for purposes of the Federal Acquisition Regulation.

The Secretary of the Treasury’s authority to issue advisory rulings and final determinations is set forth in 19 U.S.C. § 2515(b)(1), which states:

For the purposes of this subchapter, the Secretary of the Treasury shall provide for the prompt issuance of advisory rulings and final determinations on whether, under section 2518(4)(B) of this title, **an article is or would be a product of a foreign country or instrumentality designated pursuant to section 2511(b) of this title.**

Emphasis added.

The Secretary of the Treasury's authority mentioned above, along with other customs revenue functions, are delegated to CBP in the Appendix to 19 C.F.R. Part 0 - Treasury Department Order No. 100-16, 68 Fed. Reg. 28, 322 (May 23, 2003).

With regard to the surgical gowns at issue, GRI and Santé USA's request involves the issue of whether the article is a U.S.-made end product or a product of the Dominican Republic. This determination addresses the latter point, whether the article is a product of the Dominican Republic and not whether the article is a U.S.-made end product. Because the articles at issue are not wholly the growth, product, or manufacture of the Dominican Republic, our analysis must apply the substantial transformation standard, as set forth in 19 U.S.C. § 2518(4)(B)(ii).

The information submitted indicates that the surgical gowns are made chiefly from non-woven textile material. GRI and Santé USA also indicate that the goods are classified in subheading 6210.10.50, HTSUS, as an apparel product. The rules of origin for textile and apparel products for purposes of the customs laws and the administration of quantitative restrictions are governed by 19 U.S.C. § 3592, unless otherwise provided for by statute. These provisions are implemented in the CBP Regulations at 19 C.F.R. § 102.21. Section 3592 has been described as Congress's expression of substantial transformation as it relates to textile and apparel products. Therefore, the country of origin of the surgical gowns for Government procurement purposes is determined by a hierarchy of rules set forth in paragraphs (c)(1) through (c)(5) of Section 102.21.

As the finished surgical gowns are produced by processing in more than one country, their origin cannot be determined by application of the 19 C.F.R. § 102.21(c)(1), wholly obtained or produced rule, and resort must be made to 19 C.F.R. § 102.21(c)(2). Section 102.21(c)(2) states that the origin of a good is the country "in which each foreign material incorporated in that good underwent an applicable change in tariff classification, and/or met any other requirement, specified for the good in paragraph (e) of [102.21]." Section 102.21(e)(1) provides in pertinent part:

The following rules will apply for purposes of determining the country of origin of a textile or apparel product under paragraph (c)(2) of this section:

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| 6210-6212 | (1) If the good consists of two or more component parts, a change to an assembled good of heading 6210 through 6212 from unassembled components, provided that the change is the result of the good being wholly assembled in a single country, territory, or insular possession. |
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The subject merchandise is classifiable in heading 6210, HTSUS. Section 102.21(b)(6) defines wholly assembled as: "the term 'wholly assembled' when used with reference to a good means that all components, of which there must be at least two, preexisted in essentially the same condition as found in the finished good and were combined to form the finished good in a single country, territory, or insular possession. Minor attachments and minor embellishments (for example, appliques, beads, spangles, embroidery, buttons) not appreciably affecting the identity of the good, and minor subassemblies (for example, collars, cuffs, plackets, pockets), will not affect the status of a good as "wholly assembled" in a single country, territory, or insular possession."

The surgical gowns at issue are assembled in both the Dominican Republic and the United States. Therefore, the surgical gowns are not "wholly assembled in a single country, territory, or insular possession," and as a result, 19 C.F.R. § 102.21(c)(2) is inapplicable.

19 C.F.R. § 102.21(c)(3) states in pertinent part,

Where the country of origin of a textile or apparel product cannot be determined under paragraph (c)(1) or (2) of this section:

- (i) If the good was knit to shape, the country of origin of the good is the single country, territory, or insular possession in which the good was knit;
- (ii) Except for fabrics of chapter 59 and goods of heading 5609, 5807, 5811, 6213, 6214, 6301 through 6306, and 6308, and subheadings 6209.20.5040, 6307.10, 6307.90, and 9404.90, if the good was not knit to shape and the good was wholly assembled in a single country, territory, or insular possession, the country of origin of the good is the country, territory, or insular possession in which the good was wholly assembled.

As the subject surgical gowns are neither knit to shape, nor wholly assembled in a single country, section 102.21(c)(3) is inapplicable.

Section 102.21(c)(4) states, “Where the country of origin of a textile or apparel product cannot be determined under paragraph (c)(1), (2) or (3) of this section, the country of origin of the good is the single country, territory or insular possession in which the most important assembly or manufacturing process occurred.”

GRI and Santé USA assert that the most important assembly or manufacturing process is the assembly of the sleeves to the main body piece of the gown in the United States. In support of their argument, they assert that the sleeves and the body are the essential components of the gown and provide the protective surfaces that are the purpose of the finished surgical gowns; attaching the sleeves to the main body of the gown gives the gown its finished shape; and attaching the sleeves to the main body of the gown requires a high degree of skill and is the most time consuming step in manufacturing the gowns. Moreover, GRI and Santé USA argue that 19 C.F.R. § 102.21(c)(4) only allows for a single assembly or manufacturing process to be the most important assembly or manufacturing process. We disagree.

The most important assembly or manufacturing processes of the surgical gowns consist of cutting the SMS textile material to make the main body and sleeve pieces, the assembly of the sleeves, the assembly of the gown body, and the application of the plastic film to the inner face of the gown body. All these steps combined create the main pieces of the surgical gown, i.e., the sleeves and the body. They are the parts of the surgical gown that make the surgical gown a surgical gown. As a result, when the sleeve subassemblies and the surgical gown body are exported to the United States, they are clearly recognizable as an unfinished surgical gown. All that is left to do in the United States is to attach the sleeves to the gown and the neck binding to the neck opening of the gown to form the finished surgical gown.

In New York Ruling Letter (“NY”) K88449, dated August 17, 2004, CBP found that the most important assembly processes for a woman’s knitted jacket in Version A were sewing the collar to the front of the jacket; assembling the sleeve parts; attaching the cuffs; sewing the side seams; sewing the pockets to the front panels; attaching the bottom band; and sewing the zipper and placket to the garment; all of which occurred in China. The final assembly processes of a woman’s knitted jacket, such as attaching the rib knit collar to the back of the jacket and sewing

the sleeves to the jacket, that occurred in the Commonwealth of the Northern Mariana Islands, were not determinative of the country of origin. Consequently, while GRI and Santé USA argue that attaching the sleeve subassemblies to the gown body subassembly requires a high degree of skill and time, we find that, in the aggregate, the cutting of the SMS textile material for the gown body subassembly and sleeve subassembly, the assembly of the sleeves, the assembly of the gown body, and applying the plastic film to the inner face of the gown body subassembly are the most important assembly or manufacturing processes in the production of the surgical gowns.

Moreover, CBP has a longstanding practice of interpreting 19 C.F.R. § 102.21(c)(4) to include more than one assembly or manufacturing process as the most important assembly or manufacturing process for purposes of a country of origin determination, as we have demonstrated above in NY K88449. *See also* Headquarters Ruling Letter (“HQ”) H308753, dated March 11, 2021; NY N308451, dated January 9, 2020; NY N302230, dated February 8, 2019; NY N174035, dated August 5, 2011; NY N091836, dated February 12, 2010; NY N026921, dated May 2, 2008; NY N033021, dated July 14, 2008; NY N019414, dated December 3, 2007; NY L81685, dated January 31, 2005; NY L87413, dated September 1, 2005; NY L81143, dated December 30, 2004; NY C85697, dated April 23, 1998; HQ 960991, dated December 9, 1997; HQ 960884, dated November 10, 1997; HQ 958668, dated May 15, 1996.

Therefore, we find, in accordance with 19 C.F.R. § 102.21(c)(4), the country of origin of the surgical gowns is the Dominican Republic.

Accordingly, the instant surgical gowns would be products of a foreign country or instrumentality designated pursuant to 19 U.S.C. § 2511(b)(1). As to whether they qualify as “U.S.-made end product,” we encourage GRI and Santé USA to review the court decision in *Acetris Health, LLC v. United States*, 949 F.3d 719 (Fed. Cir. 2020), and to consult with the relevant government procuring agency.

HOLDING:

Based on the facts and analysis set forth above, the country of origin of the surgical gowns at issue is the Dominican Republic.

GRI and Santé USA should consult with the relevant government procuring agency to determine whether the surgical gowns qualify as “U.S.-made end products” for purposes of the Federal Acquisition Regulation implementing the TAA.

Notice of this final determination will be given in the *Federal Register*, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days of publication of the Federal Register Notice referenced above, seek judicial review of this final determination before the U.S. Court of International Trade.

Sincerely,

Alice A. Kipel, Executive Director
Regulations and Rulings
Office of Trade